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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

24247 7590 08/11/2005

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,953	HENNEN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-22* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed June 13, 2005 is acknowledged and entered. Claims 1-22 are pending and under examination.

Claim Rejections - 35 USC § 102 – Response to Applicant's Arguments

2. The rejection of claims 1-3, 7-16, 18-22 under 35 U.S.C. 102(b) as being anticipated by Tokoro (5,080,895) is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the burden of inherency is on the examiner. Specifically, it is the examiner's burden to show that the chickens of Tokoro were necessarily exposed to an antigen that caused a T-cell mediated immune response in the chickens. Applicant argues that a chicken would not necessarily be exposed to some antigen that would induce a T-cell response. Chickens are raised in controlled environments that prevent exposure of a chicken to any antigens, including Newcastle diseases virus.
  - In response to Applicant's argument, the Office maintains that Tokoro's chickens were exposed to antigens that induced T-cell immune responses. The reason that chickens are immunized with Newcastle vaccine is that chickens are exposed to NDV. If chicken accommodations were sterile, then no vaccination would ever be required. The Office maintains that Tokoro's chickens were undoubtedly exposed to a pathogen at some point before laying eggs that induced an immune response. Unless Tokoro housed the chickens in a completely sterile

environment, one would expect that Tokoro's chickens had had a T-cell immune response to some antigen.

- ❖ Applicant argues that Tokoro's description is limited to generating antibodies with antibodies that are not capable of inducing a T-cell mediated immune response.
  - In response to Applicant's argument, the emphasis on antibodies in Tokoro's description does not mean that the chickens did not actually have T-cell responses.
- ❖ Applicant argues that Tokoro does not expressly or inherently describe that the transfer factor-like component of the eggs would be useful for eliciting a T-cell mediated immune response. Applicant argues that claims 19 and 21 are allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*. Applicant argues that claim 22 is allowable since Tokoro includes no express or inherent description that administration of an extract of the eggs disclosed therein to a treated animal would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response relative to the treated animal's normal T-cell mediated immune response to at least one antigenic agent.
  - In response to Applicant's argument, the yolk or albumen of Tokoro's immunized hens is administered to other animals to induce an immune response. The fact that Tokoro does not recognize that there is a T-cell response, does not mean that there was no T-cell response. Even if Tokoro did not appreciate that transfer

factor was in the egg yolks, the egg yolks were still administered to animals to induce an immune response against pathogens.

Therefore, the claims remain rejected for reasons of record. In summary, the Office holds the position that Tokoro's chickens were at some point exposed to antigens that induced T-cell responses. Since Tokoro's chickens laid eggs from which yolks were taken and administered to animals, the transfer factor is expected to have been administered to the animals, thus increasing their T-cell repertoire.

Claim Rejections - 35 USC § 103 – Response to Applicant's Arguments

3. Claims 4-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (5,080,895) as applied to claims 1-3, 7-16 and 18-22 above, and further in view of Kirkpatrick *et al* (5,840,700), for reasons of record. The claims are drawn to a method of eliciting a T-cell mediated immune response in an animal by administering an extract of an egg including transfer factor formulated for application to the skin of an animal, nasal administration and parenteral administration. The rejection above establishes the Office's position that transfer factor was inherently present in Tokoro's product. Tokoro is silent on these routes of administration, however, one would have been motivated to use them with the product of Tokoro because Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally. Although Tokoro does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications because Tokoro suggests that any appropriate route for administration be used (col. 5, lines 29-34). One would have been motivated to administer the transfer factor via other routes

depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Tokoro would have been able to formulate it because Kirkpatrick formulates transfer factor in various mediums. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are primarily directed to the argument that claims 4-6 are allowable, among other reasons, for depending directly from claim 1, which is allowable. Claims 4-6 are additionally allowable because, without improperly relying upon the hindsight provided by the disclosure of the above-reference application, one of ordinary skill in the art would not have been motivated to combine teachings relating to obtaining transfer factor from mammalian tissues (Kirkpatrick) with teachings that related to the presence of a non-transfer factor, transfer factor-like substance in eggs (Tokoro).

In response to Applicant's arguments, claims 4-6 are not allowable because claim 1 is not allowable. With regard to the assertion that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). With regard to the assertion that there is no motivation to combine the references, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the

differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Although Tokoro does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications because Tokoro suggests that any appropriate route for administration be used (col. 5, lines 29-34). One would have been motivated to administer the transfer factor via other routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Tokoro would have been able to formulate it because Kirkpatrick formulates transfer factor in various mediums.

Conclusion

4. Claim 17 remains free of the prior art, but objected to for depending from a rejected claim.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
August 10, 2005